UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, NW
Washington, DC 20580

STATE OF NEW YORK
28 Liberty Street
New York, NY 10005

Plaintiff(s),

VYERA PHARMACEUTICALS, LLC
600 Third Ave., 10th Floor
New York, NY 10016

PHOENIXUS AG,
Hadlenstrasse 5
6340 Baar, Switzerland

MARTIN SHKRELI, individually, as an owner and former director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC
FCI Allenwood Low
Federal Correctional Institution
P.O. Box 1000
White Deer, PA 17887

and

KEVIN MULLEADY, individually, as an owner and director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC,
330 East 38th St. Apt. 54K
New York, NY 10016

Defendant(s).

Case No. 1:20-cv-00706-DLC

AFFIDAVIT OF MANISH SHAH

I, MANISH SHAH, being of full age and having been duly sworn, upon my oath, depose and say:

1. I am the President and CEO of Cerovene, Inc. ("Cerovene")

2. Cerovene Inc is a company that develops generic pharmaceutical products. Cerovene is not a party to this action.

3. In this matter, Cerovene was served with a Subpoena by the Federal Trade

Commission ("FTC").

4. In response to said Subpoena, Cerovene was required to provide the Federal Government, highly sensitive, proprietary information and communications, which would reveal years of work of proprietary information and intellectual property.

5. These documents requested included, among other things, formulas that were created by Cerovene to manufacture generic brand drugs, material as to how Cerovene manufactures those products. The documents further contained, trade secrets and patent information, pricing, costs and expenses of Cerovene, client and customer lists, suppliers including the suppliers off the Active Pharmaceutical Ingredients ("API") necessary to manufacture generic drugs, along with the processes to make these generic drugs and the entities that supply the Referenced Listed Drug, ("RLD"}.

6. The information within these documents requested and produced in the previously served subpoena are closely guarded secrets of Cerovene and were produced in this matter under the Court's issued Confidentiality Order.

7. The Parties have recognized the Highly Confidential nature of the materials and the court along with the parties agreed and marked these documents Confidential or Highly Confidential and for attorneys eyes only.

8. Many if not all of the documents requested were Highly Confidential communications with the FDA.

9. Other Highly Confidential documents were contracts that Cerovene has entered into with various suppliers. Most if not all of these Agreements have confidentiality provisions in them due to the sensitive nature of the contract's terms and conditions and the irreparable harm that would occur if the terms and even the parties to the transaction became known.

10. Cerovene does not object to these records being used, as Cerovene understands that both the plaintiff and the defendant in the instant litigation are required to use said

information to prosecute and defend their case. Cerovene does however request that the Hightly Confidential and Confidential proprietary information and other privileged documents be sealed by the court as there is no public interest in having said trade secrets revealed to the public and the release of same to the public would cause irreparable harm to Cerovene.

11. There is no overlaying public interest in releasing this Highly Confidential proprietary information and trade secrets to the public.

12. Cerovene would be severely injured and irreparably harmed if these trade secrets and communications are disclosed to the public and would give its competitors an unfair advantage including allowing competitors to gain knowledge of the processes that Cerovene uses, its intellectual property, suppliers and trade relationships and would give Cerovene's competitors inside knowledge of pricing and confidential contract terms along with those confidential relationships that Cerovene has spent years building.

13. I understand that now, release to the public of the actual exhibits is not at issue and that if the Exhibits are going to be used, I will be given the opportunity to move before the court to seal those Exhibits.

14. I do however note that many of the exhibits that have been marked are communications between Cerovene and the FDA and these documents are Highly Confidential and contain highly sensitive trade secrets of Cerovene.

15. Cerovene would be irreparably harmed by the release of said information to the public.

16. As to the Pre-Trial submissions, the release of information between the FDA and Cerovene, as well as to the release of confidential contract terms including who Cerovene obtains its API and to a lesser extent the RLD would similarly cause irreparable harm to Cerovene.

17. The generic pharmaceutical industry is highly competitive and the sourcing of material including the API is a major problem for generic manufactures such as Cerovene.

18. Literally millions of dollars can be lost simply due to a delay in the obtaining of API.

19. Often a product cannot even be developed or commercialized due to the inability to obtain API.

20. As a small generic manufacturer, Cerovene often has difficulties in obtaining API and as noted in this matter, the RLD.

21. Over the years, Cerovene has established relationships with various suppliers of API for its products and the RLD. These relationships are closely guarded secrets.

22. One needs to look no further from the instant matter to understand the problems that a generic manufacturer has relative to both the sourcing of API.

23. As such, I, on behalf of Cerovene, have reviewed the Pre-Trial material, my deposition transcript and the exhibits in this matter, which the parties seek to use relating to Cerovene.

24. I am requesting that certain portions of the material be sealed, so as not to reveal highly confidential, proprietary information of Cerovene, the release of which would cause irreparable harm.

25. This request includes those potions of Cerovene's communications with the FDA which under 21CFR20 are exempt from disclosure such as formula, process, and devises used for making, preparing, compounding or processing the trade commodities, the commercial and/or financial information of the Company, including the terms and conditions of its contracts, the data and information submitted to the FDA which constitutes a trade secret.

26. Attached as Exhibit A to the moving papers are those sections from the Plaintiff's Pre-trial submissions that Cerovene is requesting be sealed

27. Attached as Exhibit B to the moving papers are those sections of the Pre-Trial submissions from the Defendants submissions, which Cerovene is requesting to be sealed.

28. The requested portions to be sealed are highlighted in yellow and are in the format that the plaintiff and defendants have provided said information.

29. To the extent that any of plaintiff or defendant has submissions which have not been provided to Cerovene, Cerovene requests that the Court seal those records as it relates to Cerovene's submissions and communications with the FDA, the terms, conditions of our contracts and names of the API and RLD suppliers.

CEROVINE, INC.

MANISH SHAH-President

ELIZABETH PALMASANO
NOTARY PUBLIC OF NEW JERSEY
Comm. # 2433346
My Commission Expires 4/30/2023

Sworn to and subscribed before me
this 9 day of November, 2021

Notary Public